

## **REMARKS**

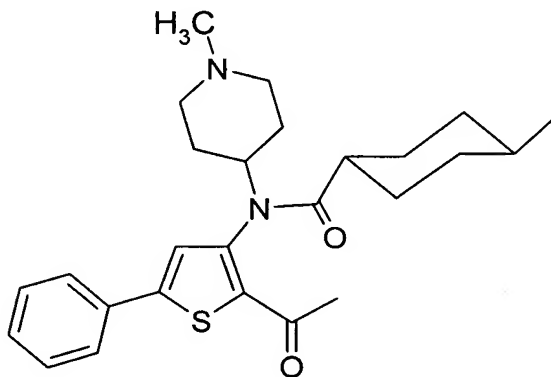
### **Amendments**

Claims 1, 10, 15, 19, and 22 are amended to correct an obvious error in punctuation.  
Claims 9, 14, 18, and 21 are amended so that the compound names are all listed consistently.

### **Election**

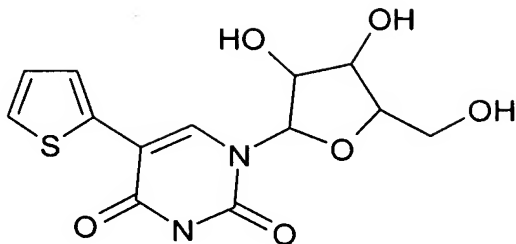
In the Office Action of August 31, 2006, it is argued that the compounds of Groups I and II have different core structures. Applicants dispute this assertion.

It is indisputable that the compounds of Group I and Group II both fall within the genus defined by formula I as set forth in, for example, applicants' claim 1. The only difference between the compounds of Group I and Group II is the definition of the group W. Hence, the remainder of the structure, presented below, is a core structure common to both the compounds of Group I and the compounds of Group II.



The above structure is acknowledged to be the core structure of the compounds of Group I in the Office Action. But, it is alleged that Group II has a different core structure, i.e., a core structure of the following formula:

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Firstly, this structure has a uracil ring directly attached to a thiophene. Clearly, this structure is not common to all compounds of Group II. For example, this structure is not present in compound of Group II wherein W is cytosine, quinine, or thymine. But, more importantly, this structure is actually not present in any of the compounds of Group II. As mentioned, the structure has a uracil ring **directly** attached to a thiophene, i.e. there is no -CO- between the thiophene ring and the group W nucleoside. In any event, this structure does not show other significant features that are clearly common to all of the compounds of Group II such as the other substituents of the thiophene ring.

The Examiner's commons regarding prodrug also do not justify restriction within a claim. Prodrugs are described in applicants' specification in the paragraph bridging pages 2-3. This description does not necessitate that a prodrug be inactive. Moreover, despite the 1985 description of prodrug used by Bundgaard, it is not necessary for a prodrug to be completely inactive. In fact, it would be beneficial for a prodrug to have some activity since then both the intact prodrug and the conversion product would exhibit activity. Thus, withdrawal of the Restriction between Groups I and II, which seeks to restrict within a single claim, is respectfully requested.

Furthermore, with respect to the claims of Group V, these claims merely recite an additional component. The search required for examination of for elected Group I and Group II completely overlaps the search required for Group V. Moreover, once the compounds of Group I and/or Group II are found to be allowable, a composition or combination encompassing such compounds will also necessarily be allowable, regardless of any additional component. The assertion that the additional ingredient may have an additive, synergistic or antagonistic effect does not impact the scope of the search or the examination. Thus, withdrawal of the Restriction

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between Groups I/II and Group V is respectfully requested.

As for Groups III-IV, upon determination that the compound are allowable, applicants will request rejoinder of the claims of Groups III-IV, pursuant to MPEP §821.04. Further, if the Restriction is withdrawn as to Group V, applicants will request rejoinder of the claims of Group VI.

**Rejection under 35 USC §103(a) in view of Kong et al. (US 6,881,741)**

Claims 1-9, 15, 18, and 23 are rejected as allegedly being obvious in view of Kong et al. (US 6,881,741). This rejection is respectfully traversed.

US 6,881,741 issued on April 19, 2005, from US Application Serial No. 10/166,031. The latter was published as US 2004/0116509 on June 17, 2004, i.e., after the filing date of the instant application (December 9, 2003). Thus, US '741 does not qualify as prior art under 35 USC §102(a) or (b). Furthermore, as discussed below, US '741 does not qualify as prior art under 35 USC §102(e) for purposes of obviousness.

As set forth on the cover page, US 6,881,741 is assigned to ViroChem Pharma Inc. The instant application is also assigned to ViroChem Pharma Inc. by virtue of the assignment recorded at reel 016331/frame 0199. The instant application and US 6,881,741 were, at the time the invention of the instant application was made, owned by Shire BioChem Inc. Both US 6,881,741 and the instant application were then subsequently assigned to ViroChem Pharma Inc. See MPEP 706.02 (I)(2). Thus, US '741 does not qualify as prior art under 35 USC §102(e). Withdrawal of the rejection is respectfully requested.

In the rejection, it is asserted that US '741 discloses a genus that encompasses the claimed compounds. It is by now well settled law that mere disclosure of a broad genus, in and of itself, does not render obvious all compounds encompassed therein. Instead, there must be some motivation that would lead one to select the particular species. In the instant case, no such motivation is presented.

See, e.g., *In re Jones*, 21 USPQ2d 1941, 1943, (Fed. Cir. 1992) wherein the Court in reversing the Board's decision of *prima facie* obviousness, disputed the Board's reliance on the Court's prior decision, *Merck & Co. v. Biocraft Labs, Inc.*, 10 USPQ2d (Fed. Cir. 1989):

We **decline** to extract from *Merck* the rule that the Solicitor appears to suggest -- that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it. .... In contrast, though Richter [the prior art relied on] discloses the potentially infinite genus of 'substituted ammonium salts' of dicamba, and lists several such salts, the claimed salt here is not specifically disclosed. Nor, as we have explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it *prima facie* obvious (emphasis added).

See also the Court's decision in *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). In that case, the Court noted that the prior art genus of diphenol compounds for use in developer compositions encompassed bisphenol A, which was used as part of a claimed toner composition. However, the Court held that this generic disclosure did not render obvious the particular claimed embodiment.

Compare also the non-precedential opinion issued by the Board in *Ex parte Rozzi*, 63 USPQ2d 1196, (Bd. of Pat. Appls. & Interf. 2002), where the Board, in reversing an obviousness rejection stated:

The Examiner does not make out a case of obviousness merely by virtue of the fact that the subject matter of a rejected claim is, to use the examiner's words, 'generically' described by the prior art.

The rejection asserts that it is obvious to pick some among many. This assertion contradicts the case law cited above. Additionally, the rejection refers to the compounds 287, 563-567, and 573 of US '741. Yet, of these compounds, only 573 exhibits a piperidine ring. US '741 discloses almost 600 specific compounds. The rejection presents no rationale as to the motivation for why one would modify, for example, compound 573, so as to arrive at a compound of applicants' claimed genus.

In view of the above remarks, withdrawal of the rejection is respectfully requested.

**Rejection under 35 USC §103(a) in view of Kong et al. (US '741) and Bundgaard**

Claims 1-9, 15, 18, and 23 are rejected as allegedly being obvious in view of Kong et al. (US 6,881,741) in combination with the article by Bundgaard. This rejection is respectfully traversed.

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As noted above, US '741 does not qualify as prior art under 35 USC §102(a) or (b), or as prior art under 35 USC §102(e) for purposes of obviousness. Withdrawal of the rejection is respectfully requested.

In the rejection, it is asserted that US '741 "disclosed the instantly claimed compounds as delineated above," referring to the prior rejection. However, as discussed above, US '741 does not describe applicants' claimed compounds, nor does US '741 provide motivation to modify the compounds disclosed therein so as to arrive at a compound of applicants' claimed genus.

The rejection asserts that "prodrug preparation is a resolution of delivery problem," citing Bundgaard. However, the rejection fails to establish that there is any suggestion in the art that the compounds of have delivery problems. Thus, there is no motivation to seek the preparation of prodrug forms. Furthermore, the asserted prior art does not suggest the significant and unexpected increase in bioavailability as shown in applicants' Example 9.

In view of the above remarks, withdrawal of the rejection is respectfully requested.

**Obviousness-type Double Patenting Rejection in view of Kong et al. (US 6,881,741)**

Claims 1-9, 15, 18, and 23 are rejected as allegedly being obvious in view of claims 1-174 Kong et al. (US '741), alone or in combination with Bundgaard. This rejection is respectfully traversed.

In the rejection, it is argued that the claims are rejected for obviousness-type double patenting for the same reasons as set forth in the rejections under 35 USC 103. The rejection under 103 is based on a broad genus and the disclosure of specific compounds set forth in the specification. However, an obviousness-type double patenting rejection can not rely on disclosure within a specification. Instead, an obviousness-type double patenting rejection must demonstrate that the **claims** of the reference patent or application render obvious the claimed subject matter. The rejection fails to present any rationale as to how the claims of US '741 render obvious applicants' claims.

Furthermore, as discussed above, the compounds cited in the rejections under 103 do not lead one of ordinary skill in the art to select a compound in accordance with applicant's claimed genus.

Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

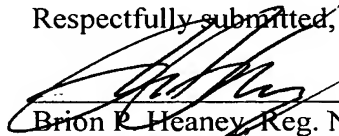
**Obviousness-type Double Patenting Rejection in view of Kong et al. (10/730,272)**

Claims 1-9, 15, 18, and 23 are rejected as allegedly being obvious in view of claims 25-101 of Kong et al. (US Serial No. 10/730,272). This rejection is respectfully traversed.

In the rejection it is argued that US Serial No. 10/730,272 claims a smaller genus of the genus of compounds claimed in the instant application. This is incorrect. The compounds claimed in US Serial No. 10/730,272 do not exhibit a piperidine ring. Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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Attorney Docket No.: VIRO-6

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